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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,296	04/20/2007	Benjamin Sredni	32040	2931

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,296	SREDNI ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/12/06; 10/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the 371 of PCT/IB04/04095 filed April 20, 2007. Claims 1-6 are being examined on the merits herein.

IDS

The Information Disclosure Statements submitted by the Applicant cites one of the references twice (US-5,610,179). As a result, the duplicate reference was crossed out on the IDS submitted 10/29/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for ammonium trichloro (dioxoethylene-O-O') tellurate, does not reasonably provide enablement for the treatment of bacterial or fungal infections in fish and crustaceans with any organic tellurium compound as set forth in the instant claims. The specification does not provide sufficient information that all organic tellurium compounds are capable of treatment of bacterial or fungal

infections in fish and crustaceans. Thus, the term organic tellurium compound is very broad as cited in claims 1, 2 and 4-6.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information that all organic tellurium compounds are capable of treating of bacterial or fungal infections in fish and crustaceans.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating bacterial or fungal infections in fish and crustaceans with any organic tellurium compound as described in claims 1, 2 and 4-6.

The nature of the invention is complex in that it encompasses the treatment said ailments using a wide array of compounds encompassed by the term "organic tellurium compound".

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass methods of treating bacterial or fungal infections in fish and crustaceans with any organic tellurium compound. There are countless possible compounds encompassed by "organic tellurium compound" for the treatments claimed. The claims are therefore much broader than the enabling disclosure.

(3). Guidance of the Specification:

The guidance given by the specification as to how effective the disclosed organic tellurium compounds are at treating the desired ailments is limited. Most of the guidance provided by the specification is directed toward ammonium trichloro (dioxoethylene-O-O') tellurate.

(4). Working Examples:

Applicant provides examples of ammonium trichloro (dioxoethylene-O-O') tellurate and its protective role against Aeromonas salmonicida infections in stressed goldfish.

(5). State of the Art:

As far as the Examiner is aware, methods of treatment using tellurium complexes is very limited.

(6). Nature and predictability of the invention

The nature of the invention is directed towards medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of an appropriate pharmaceutical carrier, a dosage for each compound as encompassed by "organic tellurium compound", the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the combination in the model system to determine whether or not the combination is effective for treating bacterial or fungal infections in fish and crustaceans. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding treatment of bacterial or fungal infections in fish and crustaceans

with any organic tellurium compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treating bacterial or fungal infections in fish and crustaceans with any organic tellurium compound as set forth in the claims.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, methods of treating bacterial or fungal infections in fish and crustaceans with any organic tellurium compound of the claims is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sredini et al. (US Patent No. 5,475,030) in view of Yada et al. (International Review of Cytology, 2002)

Sredini discloses a series of tellurium and selenium compounds of formulas A and B (column 1, line 40- column 5, line 15). Also specifically taught is ammonium trichloro (dioxoethylene-O-O') tellurate (examples 1-3; table 2, table 3).

Sredini teaches that the compounds of the invention may be administered to mammals for treatment of cancer, immune deficiencies, autoimmune diseases and infectious diseases using amounts that are effective in each condition. The treatment alleviates the symptoms of these diseases by causing the mammalian body to produce increased amounts of lymphokines. The invention also includes the in vitro production of increased amounts of cytokines such as lymphokines and or their receptors and the

use of these materials as therapeutic agents to be administered to mammals for the alleviation of cancer, immune deficiencies and infectious diseases (column 5, lines 50-61).

Sredini further teaches that the term infectious diseases includes those pathologic conditions that arise from bacterial, viral or fungus organisms that invade and disrupt the normal function of the mammalian body (column 6, lines 40-44).

Sredini teaches that the composition of the invention may be used in combination with other anti-cancer chemotherapeutic agents (column 5, lines 60-64), therefore, the treatment can be either direct or adjunct.

Further, Sredini teaches that the compounds may be utilized for veterinary purposes in the treatment of viral and immune diseases that afflict horses, ungulates and fowl (column 7, line 35-39).

Additionally, the compounds may be used as anti-bacterial or anti-viral in plants or animals (column 7, lines 46-47).

Sredini teaches that the dosage of the compounds may be administered in a range of 0.05 to 1.0 mg/kg (column 7, lines 19-24).

Though Sredini teaches administering the compounds for veterinary purposes, treating fish and crustaceans is not taught.

Yada teaches that the endocrine-immune interactions that occur in mammals, also occurs in nonmammalian vertebrates, particularly fish (page 36, 1st paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the tellurium compounds and the administration thereof

taught by Sredini could also be used to treat the same ailments in nonmammalian vertebrates, namely fish. The motivation is provided by Yada which teaches that the endocrine-immune interactions that occur in mammals, also occurs in fish. Thus one would expect with a reasonable degree of success that administration of the tellurium compounds to mammals would also be effective in treating nonmammalian vertebrates, namely fish.

Further, it would be obvious to one of ordinary skill in the art to optimize the dosage regimen on a case by case basis in order to obtain optimum dosage depending on whom the compounds are being administered to.

Generally, mere optimization of ranges will not support the, patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. In re *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

Conclusion

Claims 1-6 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617